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February 21, 2003

The Honorable Lester M. Crawford, Jr.
Deputy Commissioner of Food and Drugs
Food and Drug Administration
5600 Fishers Lane
Room 1471, HF-1
Rockville, Maryland 20857

Re. *Alex Cain, et al. v. Merck & Co., Inc. et al.*.
Docket No. CV-01-3411 (SJ)
United States District Court
Eastern District of New York/FDA Docket 02N-0471

Dear Commissioner Crawford:

We represent Merck & Co., Inc. ("Merck") and write in response to the letter addressed to you from David A. Barrett, plaintiffs' counsel in Cain v. Merck & Co., Inc., et al., Docket No. CV-01-3411 (E.D.N.Y. filed on May 29, 2001) (Johnson, J.), that the FDA has assigned Docket 02N-0471. Mr. Barrett requests an FDA inquiry into a matter that the Agency has already fully investigated and on which it has made a determination.

The FDA has already conducted a complete inquiry concerning the clinical study results on which Mr. Barrett relies, including conducting a public meeting of the FDA Arthritis Advisory Committee in February 2001. The Agency approved revised prescribing information, in effect since April 2002, that describes the very study results that Mr. Barrett cites.

In support of his request for further inquiry, Mr. Barrett relies on "a number of studies" of which "the FDA is aware." Barrett Letter at 1. Mr. Barrett does not identify those studies nor provide data from them. Mr. Barrett goes on to characterize inaccurately the results of these studies.

In granting defendants' motion to dismiss or stay plaintiffs' claim for injunctive relief, the Court in Cain found that "Plaintiffs are essentially asking this Court to determine that the findings of the [Vioxx Gastrointestinal Research ("VIGOR")] study warrant a change in the labeling and package inserts included with Vioxx and Celebrex, as well as emergency notification to all users of Vioxx and Celebrex." Cain, No. CV-01-3411, Slip Op. at 7. The

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FDA has already conducted and concluded an inquiry with respect to that study and other data related to VIOXX®. After extensive review of the data, the FDA approved revised prescribing information for VIOXX® on April 11, 2002, and did not require emergency notification to all VIOXX® users.

No further inquiry or action is necessary on the part of the Agency, and the FDA should decline Mr. Barrett's request accordingly.

Sincerely yours,

Theodore V. H. Mayer

cc: The Honorable Sterling Johnson, Jr.
David A. Barrett, Esq.
Steven Glickstein, Esq.
James D. Arden, Esq.
FDA Dockets Management Branch